

REMARKS

Upon entry of the following amendments, claims 1-36 constitute the pending claims in the present application. No claims are cancelled or objected. Claims 6, 8, and 18-30 are withdrawn. Claims 1-5, 7, 9-17 and 31-34 stand rejected.

New Claims

Support for new claim 35 can be found throughout the specification including page 5, lines 23-25; page 30, lines 2-23; and Example 30, page 78. Support for new claim 36 can be found throughout the specification including page 5, lines 26-28 and Example 30, page 77. Applicants assert new claims 35 and 36 do not constitute new matter.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the prior Office Action.

Telephonic Interview

Applicants note with appreciation the telephonic interview held with the Examiner and his supervisor on April 24, 2008. Briefly, Applicants' representatives pointed to Figure 1 as an example of an embodiment of the claimed invention that illustrates linking molecules having two inclusion guests that interact selectively and non-covalently to form an inclusion complex with inclusion hosts of the polymer. Applicants' representatives highlighted Example 27 in the specification as an example of a linking molecule that bears two inclusion guests, and Example 11 as an example of a linking molecule with three inclusion guests. Each linking molecule can bind an inclusion host with each inclusion guest, thereby non-covalently crosslinking the polymer. Applicants' representatives discussed how the cited art fails to teach or suggest polymer crosslinking via inclusion complex formation, as contrasted with the art-recognized strategy of covalent crosslinking of polymers. Applicants pointed out that advantages of the non-covalent crosslinking technology include the high selectivity and mild conditions for establishing interactions between inclusion hosts and inclusion guests, as compared to standard covalent crosslinking agents that might undergo side reactions with other molecules, such as therapeutic agents or excipients, present in the reaction medium.

Claim Rejections – 35 U.S.C. 103(a)

In the previous Office Action mailed July 2, 2007, the Office rejected claims 1 and 15-17 under 35 U.S.C. 103(a) as being unpatentable over Middleton et al. Synthetic biodegradable polymers as orthopedic devices, Biomaterials 21 (2000), pgs. 2335-2346 (“Middleton”) and USPGPUB 2001/0034333 A1 (“Kosak”). It appears that the rejection is maintained in the instant Office Action based upon language on pages 2-4, although such a rejection not specifically stated.

The Office states that “the instant specification is absent any such disclosure directed to unexpected results due to the *alleged* distinct structural features and properties” (emphasis added) vis-à-vis the teachings of Middleton and Kosak. Applicants again submit, pursuant to MPEP 2142, “[t]o establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants assert that the Office has not satisfied this requirement.

As Applicants previously argued, neither Middleton nor Kosak teach or suggest non-covalent crosslinking of polymers. Furthermore, the neither Middleton nor Kosak teach or suggest crosslinking of polymers via inclusion complex formation, let alone crosslinking of polymers via linking molecules “wherein the linking molecules crosslink the polymer through inclusion complexes.” The Office points to paragraphs [0082] and [0091] of Kosak, stating that they “adequately address and the limitation [sic] in applicants’ specification (pg 33) and instant claims” and “are replete with representative examples and/or embodiments of linking molecules cross linking the polymer through inclusion complexes.” Applicants respectfully point out that the covalent crosslinking as disclosed in Kosak is fundamentally different from *non-covalent* crosslinking disclosed in the instant application. Paragraph 82 teaches “completely entrapped larger guests such as proteins, polypeptides, and nucleic acids.” This paragraph teaches only “completely entrapped” molecules. Nowhere is it taught or suggested that these entrapped molecules can be used to crosslink the polymer. Nor does Kosak teach crosslinking of polymers through inclusion complexes. Paragraph 91 discusses biocleavable cross-linking agents, but does not teach or suggest that the agents crosslink non-covalently through inclusion complex formation.

Applicants submit that the linking molecules and the polymers of the presently claimed invention are separate and distinct entities (see page 5, lines 14-16 of the description). To demonstrate this notion, Applicants draw the Examiner's attention to Figure 1, which illustrates one embodiment of the claimed invention. In this figure, the molecules shown in A (the polymer) bear inclusion hosts (represented as trapezoids), while the molecule in B (the linking molecule) features inclusion guests (represented as circles). A and B are distinct entities that exist as separate molecules *even when the polymer is crosslinked*. The polymer composition shown in P shows that when A and B are combined, the linking molecules associate non-covalently with the polymer by forming inclusion complexes, thereby crosslinking the polymer.

The Office states "[i]t would be instantly apparent to the skilled artisan that cyclodextrin moieties and linking molecules crosslink the polymer through such inclusion complexes," but the Office does not indicate where Middleton or Kosak teach or suggest crosslinking through inclusion complexes in which a polymer and a linking molecule are distinct entities, or even crosslinking through inclusion complex formation. As such, these references cannot properly form the basis for the present obviousness rejection. For the above reasons, Applicants assert that Middleton and Kosak, either alone or in combination, fail to teach or suggest all the features of present claims 1 and 15-17. Consequently, Applicants request reconsideration and withdrawal of the rejection over these references.

The Office rejects claims 1-5, 7, 9, 10-17, and 31-34 under 35 U.S.C. 103(a) as being unpatentable over Middleton, Kosak, and Rohrbach et al, U.S. Pat. No. 5,098,793 ("Rohrbach"). The Office states "Rohrbach et al. teach the versatility of cyclodextrin moieties" and that "[t]he usefulness of these cyclodextrins arises from their ability to reversibly form inclusion complexes, or clathrates, with many types of compounds." Further, the Office states that "Rohrbach et al. teach the cyclodextrin [including] guest molecules that the skilled artisan would instantly recognize as obvious over instant claims 2-5 (column 5, lines 62-63 and column 6, lines 14-63).

Applicants submit, pursuant to MPEP 2142, "[t]o establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim

limitations.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants assert that, even in light of the additional reference (Rohrbach), the Office has not satisfied this requirement.

Applicants submit that these sections of Rohrbach teach the covalent attachment of cyclodextrin with polyfunctional agents. Nowhere does Rohrbach teach or even suggest non-covalent crosslinking of a polymer, let alone crosslinking through inclusion complexes. Certainly Rohrbach does not teach or suggest crosslinking of a polymer via linking molecules, wherein each linking molecule comprises at least two moieties that form inclusion complexes with the inclusion hosts. In fact, the notion of an “inclusion complex” is not even mentioned in these paragraphs or anywhere else in the disclosure. There can be no question that these sections of Rohrbach fail to teach or suggest crosslinking of a polymer through inclusion complexes.

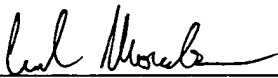
For reasons stated above, Middleton, Kosak and Rohrbach, either alone or in combination, fail to teach or suggest all the elements of the instant claims. Consequently, Applicants request removal of the rejection.

CONCLUSION

Applicants believe no fee beyond that required for the extension of time mentioned above is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. ITI-P01-010 from which the undersigned is authorized to draw.

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Respectfully submitted,

By 

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